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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,770	07/01/2003	James E. Brewer	A03P1047	4998
36802	7590	03/02/2006	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			GEDEON, BRIAN T	
			ART UNIT	PAPER NUMBER
			3766	
DATE MAILED: 03/02/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/612,770	Applicant(s) BREWER ET AL.	
	Examiner Brian T. Gedeon	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-20 is/are rejected.
- 7) ☒ Claim(s) 8,9 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/1/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-7, 10-12 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sloman et al. (US Patent no. 6,738,669) in view of Dahl et al. (US Patent no. 6,976,967).

In regards to claims 1 and 15, Sloman et al. discloses an implantable medical device 10 for multichamber cardiac stimulation that delivers an electrical pulse to one of the chambers of the patient's heart, col 7 lines 47-63. The electrical signals can be delivered to any chamber of the heart, col 11 lines 39-42. Upon delivery of an electrical pulse, far-field sensing occurs, col 11 lines 53-58. For example, if right ventricle stimulation occurs, far-field sensing by a combination of electrodes may occur in the right atrium lead 20 or coronary sinus lead 24, col 12 lines 17-21. Dahl et al. discloses an implantable lead 4 with sensing unit receiving a signal transmitted from a lead disposed in the heart and determines a change in dimension of the heart due to the heart beating, col 6 lines 26-33. Therefore it would have been obvious to one of ordinary skill in the art to use the lead described by Dahl et al. with the methods and apparatus disclosed by Sloman et al. in order to assess the qualitative and quantitative

aspects of cardiac output relating to the pumping of the heart, capacity, heart rate, and similar cardiac data and better diagnose and treat cardiac symptoms.

In regards to claim 2, Sloman et al. states that the sensing and stimulating electrodes may have a unipolar configuration, col 8 lines 8-12.

In regards to claim 3, Sloman et al. shows that stimulation can take place in the right ventricle, col 12 lines 17-21.

In regards to claim 4, Sloman et al. discloses several leads for placements in the right ventricle with a ring electrode, col 6 lines 47-60.

In regards to claim 5, Sloman et al. teaches that there can be a sensing electrode placed in the superior vena cava, col 6 lines 47-60.

In regards to claim 6, Sloman et al discloses that sensing can occur in a chamber, col 6 lines 47-60, and can occur in any of the four chambers of the heart, col 8 lines 13-17 and col 12 lines 17-21.

In regards to claim 7, Sloman et al. shows that sensing can occur in a unipolar fashion, col 12 lines 17-21.

In regards to claims 10-12, Sloman et al. substantially describes the claimed invention except for the steps of determining a ventricular distance, ventricular volume, or a ventricular distance. Dahl et al. shows that determining the change in dimension of the heart may include a change in the distance between portions of the heart, col 5 lines 40-67. A sensed change in dimension would obviate a calculation of volume since volume is related to spatial dimension. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the lead of Dahl et al.

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in combination with the leads of the device and methods of Sloman et al. in order to electrically determine chamber contraction and volumetric output in combination with electrical stimulation therapy.

In regards to claim 14, Sloman et al. states that after a stimulation pulse is delivered to a portion of the heart, the far-field sensing is used in conjunction with other processes to determine if capture in that portion of the heart was successful. If it was determined that capture was unsuccessful, another stimulation pulse is then applied, col 13 lines 26-37.

In regards to claim 16, Sloman et al. substantially describes the claimed invention including a battery for power 110, and stimulation leads 30 having a tip 32 and ring electrode 34, col 6 lines 46-60.

In regards to claim 17, the sensing means of Sloman et al. includes a sensing circuit 82 and 84 coupled to sensing leads 20 and 30, col 8 lines 13-17. Each lead has a plurality of electrodes, col 6 lines 20-60.

In regards to claim 18, the implantable stimulation device 10 has a programmable microcontroller 60 that controls stimulation therapy and processes all incoming signals, col 7 lines 36-47.

In regards to claim 19, Sloman et al. discloses an implantable device 10 with a housing 40, referred to as the "case" or "can", and it may act as the return electrode for all unipolar modes, col 7 lines 5-19. The device has a plurality of leads 20, 24, and 30 connected to the device and is implantable within many structures of the heart, col 6 lines 19-27. Pulse generators 70 and 72 generate stimulation pulses for delivery to the

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implantable leads, 20, 24, and 30, col 7 lines 48-63. Sensing circuits 82 and 84 are used upon delivery of an electrical pulse, for far-field sensing occurs, col 8 lines 13-17 and col 11 lines 53-58. For example, if right ventricle stimulation occurs, far-field sensing by a combination of electrodes may occur in the right atrium lead 20 or coronary sinus lead 24, col 12 lines 17-21. Dahl et al. discloses an implantable lead 4 with sensing unit receiving a signal transmitted from a lead disposed in the heart and determines a change in dimension of the heart due to the heart beating, col 6 lines 26-33. Therefore it would have been obvious to one of ordinary skill in the art to use the lead described by Dahl et al. with the methods and apparatus disclosed by Sloman et al. in order to assess the qualitative and quantitative aspects of cardiac output relating to the pumping of the heart, capacity, heart rate, and similar cardiac data and better diagnose and treat cardiac symptoms.

In regards to claim 20, Sloman et al. possesses one or more ventricular leads, col 6 lines 13-18. Lead 24 is configured for the left ventricle, col 6 lines 40-35.

2. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sloman et al. (US Patent no. 6,738,669) in view of Dahl et al. (US Patent no. 6,976,967) and further in view of Mulligan et al. (US Patent no. 6,438,408).

Sloman et al. in view of Dahl et al. substantially describes the claimed invention except for relating the change in cardiac dimensions to congestive heart failure.

Mulligan et al. uses pairs of impedance electrodes 170, 172, 174, 176 to measure the heart chamber volume, col 16 lines 28-49. The methods and apparatus of Mulligan et al. are believed to benefit patient's suffering from heart failure, including congestive

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heart failure, col 28 lines 2-4. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to monitor the physical geometry of the heart in order to better assess and electrically treat cardiac abnormalities.

Allowable Subject Matter

3. Claims 8, 9, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Information Disclosure Statement

4. The information disclosure statement filed 01 July 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Therefore the Examiner did not consider the cited non-patent literature.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mulligan et al. (US 2005/0027323) discloses an implantable medical device for monitoring cardiac blood pressure and chamber dimension. Ben-Haim et al. (US Patent no. 6,891,091) discloses a method and apparatus for rapidly

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generating an electrical map of a chamber of the heart utilizing a catheter. Budd et al. (US Patent no. 5,662,108) discloses a mapping catheter for mapping a heart chamber using active electrodes to impose an electrical field within a chamber of the heart, and passive electrodes to record potentials.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272 6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brian T. Gedeon
Patent Examiner
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Robert E. Pezzuto
Supervisory Patent Examiner
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BTG